

Polarimetric Analytical Method: The Importance in the Determination of Pharmaceutical Active and Inactive Ingredients

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Editorial

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Abbreviations: LC: Liquid Chromatographic, API: Active Pharmaceutical Ingredients, FPP: Finished Pharmaceutical Product.

Editorial

Molecules that make up living things or metabolized by living things tend to be chiral. Chiral compounds (optical isomers), are a specific case of stereoisomers and are distinguished by having enantiomeric counterparts with identical chemical properties in nonchiral environments however, differing in the way they rotate a plane of polarized light. As chirality becomes more appreciated amongst research scientists, tools to measure it increase in importance in analytical laboratories. Such tools involve the use of polarimeters and polarimetric liquid chromatographic (LC) detectors [1].

Polarimetry is a sensitive, non-destructive analytical method employed to measure the optical activity of inorganic and organic compounds. An optically active compound permits linearly polarized light to be rotated when passed through it. The molecular structure and concentration of optically active molecules in the substance determine the amount of optical rotation. The property of optical rotation is specific to a compound, and it is related to its concentration in solution [2]. Biots law (Equation 1) allows specific rotation of each optically active substance to be evaluated.

$$[\alpha]_T \lambda = \alpha / c \times l \text{ (Equation 1)}$$

Where $[\alpha]$ = specific rotation, α = optical rotation, λ = wavelength, T = temperature, c = concentration (g/ml), l = optical length (cm).

In order to determine the concentration and purity of optical chemical substances, a polarimetric method is often used. The analytical method is simple, accurate, precise and sensitive and has found its applications in research industry (isolation and identification of unknown optical compounds, investigating kinetic reactions, distinguishing between optical isomers etc), pharmaceutical industry (analysis of analgesics, antibiotics, antihypertensives, steroids, tranquilizers, vitamins etc.), flavor, fragrance and essential oil industry (analysis of camphor's, citric acid, gums, lemon oil, orange oil spearmint oil etc.), food industry (analysis of various starches, monosaccharide's, disaccharides etc), chemical industry (analysis of biopolymers, natural and synthetic polymers etc.).

Despite the wide applicability of the analytical method, the present paper will attempt to provide comprehensive contributions of polarimetric method to pharmaceutical industry. A pharmaceutical industry deals mainly on the manufacture of active pharmaceutical ingredients (API), inactive pharmaceutical ingredients (excipients) and pharmaceutical dosage forms.

A pharmaceutical dosage form is the physical form of a dose of a chemical substance used as a drug or medication intended for administration [3]. Pharmaceutical dosage form can be classified into solid type (tablets, capsules, lozenges, powder and granules etc.), semi-solid type (creams, ointments, gels, pastes etc.), pharmaceutical inserts (suppositories, implants etc.), liquid types (solutions, suspensions, emulsions, inhalations etc.), delivery systems (transdermal system, ocular system, intrauterine system etc).

The production of pharmaceutical dosage forms involves the utilization of both active and inactive ingredients. A pharmaceutical active ingredient (API) is any substance or mixture of substances used in a finished pharmaceutical product (FPP), intended to furnish pharmacological activity or to other direct effect in the diagnosis, cure, mitigation, treatment or prevention of disease or to affect the structure and physiological functions of the body [4].

A pharmaceutical inactive ingredient (excipient) is a substance (natural, synthetic, or semi-synthetic in origin) other than the active pharmaceutical ingredient (API) that is intentionally included in an approved drug delivery system or a finished drug product to protect, support or enhance stability, bioavailability and patient acceptability [5]. It may also assist in product identification and enhance the overall safety or function of the product during storage or use. Depending on the intended use, an excipient in one drug product may be an active ingredient in another drug product. Such an excipient is often referred to as "atypical active" or "dual-active" excipient.

Although a significant part of the quality of a finished pharmaceutical dosage form depends on the quality of the active pharmaceutical ingredients (APIs) used for its formulation, legislation requires the identification and assay of both active and inactive ingredients used in the manufacture.

Polarimetric analytical method is one of the official (compendia) methods (titration, spectroscopy, chromatography etc.) used in the identification and assay of pharmaceutical active and inactive ingredients [6]. Such inactive ingredients include but not limited to: lemon oil, orange oil spearmint oil, starches, monosaccharides, disaccharides, natural and synthetic polymers. Several active ingredients (in bulk or dosage form) have been analyzed by this method of which some

are atropine sulfate, adrenaline, ampicillin sodium, apomorphine hydrochloride, beclomethasone, benzyl penicillin, carbidopa, cephalexin, dexamethasone, digitoxin, ephedrine, ethinyloestradiol, griseofulvin, hyoscyamine sulfate, ibuprofen, levodopa, naproxen, pantothenic acid calcium, testosterone etc.

In conclusion, literature has shown that through the use of polarimetry, one can identify and determine concentrations of various pharmaceutical active and inactive ingredients. It may be the only conventional means for distinguishing optically active isomers from each other. Although, sodium (Na) spectral line at 589 nm is often used, it has been found that the use of lower wavelengths, (such as those available with the mercury lamp lines in a photoelectric polarimeter), provide advantages in sensitivity thus giving rise to reduction in the concentration of the test compound. The acceptance criteria for the assay test, is based on its accuracy and precision. Utilizing a polarimetric detector in HPLC, one can differentiate between enantiomers, or may find it more appropriate for the detection of certain samples found in nature. Finally, accuracy, precision, sensitivity and high versatility make polarimetric analytical method an important analytical tool for research applications as well as for quality control of pharmaceutical compounds.

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